K113470

NIPRO MEDICAL CORPORATION

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510(k) Summary - NIPRO SafeTouch Huber Infusion Set

(21 CFR 807.92)

OCT 17 2012

1. **Submitter:** Nipro Medical Corporation
   FDA Registration No: 1056186

   Contact Person: Jessica Oswald
   Prepared on: 21 November 2011

2. **Trade Name:** NIPRO SafeTouch Huber Infusion Set

   Common Name: Huber Infusion Set

   Classification Name: Intravascular Administration Set

   Classification Code: FPA (per 21 CFR 880.5440)
   Class II

3. **Predicate Device:** NIPRO SafeTouch Huber Infusion Set (K081210)

4. **Device Description:**
   The Nipro SafeTouch Huber Infusion Set is a standard non-coring Huber type needle and administration set with an integrated safety mechanism to prevent accidental needle sticks. The device is designed for use with a vascular access infusion system and is intended for use as an intravascular administration set to access surgically implanted subcutaneous vascular ports in a standard manner for the purposes of fluid or drug infusion and blood sampling.

5. **Indication for Use:**
   This product is a safety intravascular administration set and is indicated for the administration of fluids and drugs, or blood sampling through a surgically implanted vascular port. Secondly, it incorporates a safety mechanism to help protect against exposure to blood borne pathogens caused by accidental needle stick injuries.

6. **Technological Characteristics**
   The basic structure of the device consists of a needle, needle tube, wing unit, needle hub, flexible tubing and luer connector. This device is also available with a clamp, Y-mixing tube and a joint tube. The needle is bent at a 90° angle and is available in gauges 19, 20, 22 and 24 and in lengths of ½" - 1 ½".
   The device is supplied in three basic configurations:
   1. Type A: Y-site with rubber button
   2. Type B: Without Y-site

3. Type C: Y-site with luer lock

Safety Mechanism

Following conventional placement of the SafeTouch Huber Infusion Set into the implanted port and completion of either the prescribed infusion of fluids or blood sample withdrawal the device may then be withdrawn from the patient. The safety mechanism enables the clinician to retract the needle into a shield as the needle is removed from the patient. This shield locks over the needle to prevent exposure to blood borne pathogens through accidental needlestick injuries. The safety mechanism is not passive, but it is integral. For activation, place one hand on the wings of the SafeTouch Huber Infusion Set to secure the port. With the other hand grasp the lever located on top of the needle hub and pull upward. This will remove the needle from the patient and lock the needle into the safety shield. Safety Mechanism activation is verified by an audible or tactile click.

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7. Performance Testing

Testing of the NIPRO SafeTouch Huber Needle Infusion Set was completed in conformance with the following standards:

Reference Number	Standard Title
ISO 8536-4:2010	Infusion equipment for medical use, Part 4: Infusion sets for single use, gravity feed
ISO 10555-3:1996	Sterile single use catheters, Part 3: central venous catheters
ISO 7864:1993	Sterile hypodermic needles for single use
ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1:General requirements
ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Test for In Vitro Cytotoxicity
ISO 10993-4:2002	Biological Evaluation of Medical Devices – Selection of Test for Interaction with Blood
ISO 10993-10:2002	Biological Evaluation of Medical Devices – Test for Irritation and Delayed-Type Hypersensitivity
ISO 10993-11:2006	Biological Evaluation of Medical Devices – Test for Systemic Toxicity
IAEA-TECDOC-539	Guidelines for Industrial Radiation Sterilization of Disposable Medical Products (Cobalt-60 Gamma Irradiation)
USP 31	<151> Pyrogen Test (USP Rabbit Test)
USP 31	<161> Transfusion and Infusion Assemblies and Similar Medical Devices
JIS T3221:2005	Single-use needle for infusion port
JP15	The Japanese Pharmacopoeia, Fifteenth Edition
ASTM D4169-05	Standard Practice for Performing Testing of Shipping Containers and Systems

NIPRO SafeTouch Huber Infusion Set successfully met the requirements for these standards.

In addition, it met or exceeded the acceptance criteria for the following performance tests:

Performance Test Name	**Acceptance Criteria**
1. Safety mechanism activation force	≤ 8.4 N
2. Safety mechanism activation breakage force	≥ 25.2 N
3. Safety mechanism deactivation force	Needle breaks before deactivation
4. Flow rate	19G: 41-52 ml/min
	20G: 24-38 ml/min
	22G: 10-15 ml/min
	24G: 4-6 ml/min
	Predicate Device 20G
5. Air leakage – pressure endurance	Must show no signs of air leakage of 50 [kPa] for 15 seconds.
6. Set Leakage – Endurance test	With y-site: 1.8MPa Without y-site: 3.7MPa
7. Wrapping paper leakage	Must not leak under the condition of 1.1[kPa] for 10 seconds.
8. Cannula/Hub adhesive strength measurement	19G: ≥ 69 N
	20G: ≥ 54 N
	22G: ≥ 34 N
	24G: ≥ 22 N
9. Popping needle tip inspection	No sound of puncture popping noise.
10. Tensile Adhesive strength a. Hub / tube b. Y connector / tube c. Y connector / tube d. Connecting tube / connector	Must withstand a static tensile force of 15[N] for 15 seconds.
11. Test for particulate matter	Contamination Index ≦ Na - Nb 90
12. Injection Site (rubber button)	Must show no signs of air leakage of 50 [kPa] for 15 seconds.
13. Transportation Testing	Withstand distribution environment

8. Substantial Equivalence

The Nipro SafeTouch Huber Infusion Sets are identical in physical properties, materials, configurations and having the same intended use as the predicate device (i.e., the original Nipro SafeTouch Huber Needle Infusion Set). Although the manufacturing process for the needle bevel has been modified, performance testing shows that the performance of the new Nipro SafeTouch Huber Infusion Sets is similar in most performance test and is significantly better in the Coring Test. Therefore, no new issues of safety or effectiveness are introduced by these changes.

Specification	**510(k) Nipro SafeTouch Huber Infusion Sets**		**Predicate Nipro SafeTouch Huber Infusion Sets**	
Physical and Material				
Needle	**Components**	**Materials**	**Components**	**Materials**
	Cannula	Stainless Steel	Cannula	Stainless Steel
	Hub	PVC	Hub	PVC
	Needle Tube Cap	PP	Needle Tube Cap	PP
Sharp Injury Prevention	Wing Unit	PP	Wing Unit	PP
	Over Cap	PP	Over Cap	PP
	Protector	PC	Protector	PC
Tube	Tube	PVC	Tube	PVC
	Clamp	POM	Clamp	POM
Connector	Rubber Button	IR	Rubber Button	IR
	Rubber Button Cap	PVC	Rubber Button Cap	PVC
	Luer Connector	PC	Luer Connector	PC
	Leur Cap	PP	Leur Cap	PP
Bond	Epoxide-based adhesive		Epoxide-based adhesive	
	Urethane-based adhesive		Urethane-based adhesive	
Lubricants	Silicone oil		Silicone oil	
Available Configurations	Type A: Y-site with rubber button Type B: Without Y-Site Type C: Y-site with luer lock		Type A: Y-site with rubber button Type B: Without Y-Site Type C: Y-site with luer lock	
Mechanical				
Instructions for Use	Same		Same	
Operational				
Device Type	Standard non-coring Huber needle with an integrated safety mechanism.		Same	
Safety Mechanism	For activation, place one hand on the wings of the SafeTouch Huber Infusion Set to secure the port. With the other hand grasp the lever located on top of the needle hub and pull upward. This		Same	

Specification	510(k) Nipro SafeTouch Huber Infusion Sets	Predicate Nipro SafeTouch Huber Infusion Sets
	will remove the needle from the patient and lock the needle into the safety shield. Safety Mechanism activation is verified by an audible or tactile click.	
Biological	Biocompatibility tests were performed according to ISO 10993 Parts 4, 5, 10 and 11 as a prolonged duration, indirect blood path contacting device.	Same
Sterilization Method	Ethylene oxide	Same

PVC: polyvinyl chloride, PE: polyethylene, PP: polypropylene, POM: polyoxymethylene, PC: polycarbonate, IR: isoprene rubber
PEI: polyetherimide

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2012

Nipro Medical Corporation
Ms. Jessica Oswald
Regulatory Affairs
3150 North West 107TH Avenue
Miami, Florida 33172

Re: K113470
Trade/Device Name: Nipro SafeTouch Huber Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 10, 2012
Received: October 11, 2012

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

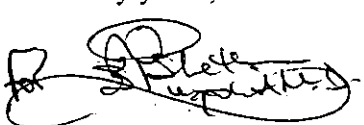
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___x____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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